United States Attorney Michael J. Sullivan District of Massachusetts

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NEW JERSEY COMPANY AGREES TO PLEAD GUILTY TO KICKBACKS AND CONSPIRACY CHARGES AND PAY MORE THAN \$22 MILLION DOLLARS IN CRIMINAL FINES.

Boston, MA....United States Attorney Michael J. Sullivan and Warren T. Bamford, Special Agent in Charge of the Federal Bureau of Investigation - New England Field Division; Susan J. Waddell, Special Agent in Charge of the Department of Health and Human Services - Office of Inspector General announced today that **BIOVAIL PHARMACEUTICALS**, **INC**, a corporation headquartered in Bridgewater, New Jersey, has agreed to plead guilty to conspiracy and kickback charges and to pay a criminal fine of \$22,243,590. These charges concern various actions engaged in by **BIOVAIL PHARMACEUTICALS**, **INC**. and its employees to carry out a program known as the "PLACE" (Proving Long Acting Through Experience) program, whereby **BIOVAIL PHARMACEUTICALS**, **INC**. paid or cause to be paid up to \$1,000 to thousands of physicians and others in order to induce them to prescribe and/or recommend the drug Cardizem, L.A.

According to the Information filed by the Government in connection with the plea agreement, as part of their promotion of Cardizem, L.A., beginning in March 2003, **BIOVAIL PHARMACEUTICALS, INC.** implemented a program known as the PLACE program. The PLACE program paid physicians and other prescribers up to \$1,000 for enrolling between 11-15 patients in the program, causing patients to fill prescriptions for Cardizem, L.A. These included prescriptions that were paid for by Medicaid. The first phase of the PLACE program required the prescribing medical professionals (e.g. physicians, nurse practitioners, physician's assistants) to enroll in the program and complete a 2 page, 10 multiple choice questionnaire that did not usually take the prescriber more than 10 minutes to complete. Under this initial part of the program, the prescribers were paid \$250.

The second phase of the PLACE program provided that if the medical prescriber returned the final questionnaire, they would be paid, in addition to the initial \$250 payment, as follows: (1) an additional \$250 if they enrolled between 1 and 5 patients; (2) an additional \$500 if they enrolled between 6 and 10 patients; and (3) an additional \$750 if they enrolled between 11 and 15 patients.

These payments exceeded the reasonable fair market value of the medical prescribers' time necessary to enroll these patients and complete the final questionnaire. The physicians and other medicine prescribers were told that in order to receive the payment they also had to track the patients' experience on Cardizem, L.A. for three regularly scheduled visits. These visits were nothing more than the routine visits and required no additional work for the prescriber.

The stated objectives of the PLACE program included to accelerate the uptake of prescriptions for Cardizem, L.A. among primary care physicians. **BIOVAIL PHARMACEUTICALS, INC.** did not design or implement the PLACE program in a way calculated to provide new or meaningful scientific data about whether Cardizem, L.A. worked better than other available drugs.

The investigation of this matter did not implicate the current management team of Biovail Corporation in the conduct described in the Information.

The case was investigated by the Federal Bureau of Investigation and the Department of Health and Human Services Office of Inspector General. The case is being handled by Assistant U.S. Attorney Sara Miron Bloom. The investigation is continuing.

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